CHAPTER 7
SECTION 7.1

PHARMACY

Issue Date: March 3, 1992
Authority: 32 CFR 199.4(b)(2)(v), (b)(3)(iii), (b)(5)(v), (d)(3)(vi), (e)(11)(i), 32 CFR 199.5(d)(12), and 32 CFR 199.17

I. POLICY

A. Retail Services

1. The Managed Care Support (MCS) Contractor shall provide an integrated retail prescription service through a common pharmacy patient profile system in each TRICARE region to all Military Health System (MHS) TRICARE/CHAMPUS-eligible beneficiaries. Medicare eligible beneficiaries affected by Base Realignment and Closure (BRAC) may also use the retail pharmacy services (see Chapter 7, Section 7.2). As part of the Supplemental Program and the TRICARE Prime Remote program, active duty service members may use the contractor's retail pharmacy network under the same contract requirements as other MHS eligible beneficiaries, except that active duty service members will have no deductibles and copayments or cost-shares.

2. A TRICARE retail network pharmacy is required to substitute generic drugs listed with an "A" rating in the current Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) published by the FDA and generic equivalents of grandfather or Drug Efficacy Study Implementation (DESI) category drugs for brand name drugs.

NOTE: TRICARE retail network pharmacies may dispense a brand name drug having a generic equivalent only if the prescribing physician substantiates the medical necessity of the brand name drug in lieu of the generic equivalent.

3. When TRICARE Prime enrollees use pharmacies other than the TRICARE retail network pharmacies, contractors will process the claims under Point of Service provisions unless the enrollee is out-of-area and has an authorization from the Health Care Finder.

4. Prescription quantities shall not exceed the lesser of a 90-day supply or the maximum quantity limit listed at www.pec.ha.osd.mil/nmop/nmophome.htm. The original prescription and the number of authorized refills shall not result in more than a 12-month supply. The contractor may override quantity limitations when medical documentation justifies a need for a higher dose. This must then be documented for the patient's future refills.

5. Prescriptions for controlled substances (Schedule III, IV, V) shall not exceed the lesser of a 30-day supply with a maximum of 5 refills in a 6 month period or the quantity limit listed at www.pec.ha.osd.mil/nmop/nmophome.htm. The exception being, controlled substances used for seizure control may be dispensed in up to 90-day quantities with one refill.

6. Schedule II controlled substance prescriptions shall not exceed the lesser of a 30-day non-refillable supply or the quantity limit listed at www.pec.ha.osd.mil/nmop/nmophome.htm. The exception being, drugs used for treating Attention Deficit Disorder may be dispensed in up to 90-day quantities.

7. Pharmacies shall not submit a claim for any new or refilled prescription not picked up by, on behalf of, or delivered to, the patient, nor submit a claim for returning the medication to stock. Pharmacies must be able to validate by an independent audit.

8. Outpatient deductible amounts do not apply to TRICARE Extra or Medicare BRAC prescription claims.

9. Compounding will be done at the same dispensing fee as all other prescriptions filled under the contract.

10. TRICARE Retail Network Pharmacy Services

a. The TRICARE retail network pharmacy shall have the capacity to process telephonic refill requests.

b. Prescriptions for controlled substances written by providers who do not have individually assigned DEA numbers shall not be accepted.

c. The contractor shall implement in their retail network pharmacies a formulary control based on the most current DoD Pharmacy and Therapeutics Committee direction listed at www.pec.ha.osd.mil/nmop/nmophome.htm.

11. Utilization Management/Quality Management/Quality Control

a. The contractor's quality assurance/improvement program shall include a system of standard operating procedures routinely updated; technical personnel training; quality control records for compounded or prepackaged medications; medication order verification prior to packaging for shipping; an error prevention program with error documentation and reporting; drug product defect reporting; proper management of drug recalls; problem reporting to the Contracting Officer's Representative, the Lead Agent, and appropriate agencies; and maintenance of minutes of QA/QM meetings.

b. The contractor's computer system that performs the pharmacy reporting must be in conformance with the National Council of Prescription Drug Programs (NCPDP) Telecommunication Standards Manual (Version 3.2).

c. The contractor shall establish and maintain a database system that contains patient profiles, medication histories, patient/provider special requests, allergy screens,

interaction information and prescription tracking information, and the capability to extract ad hoc reports.

d. The contractor shall install and maintain a toll-free line with standard modem access for MTF pharmacy personnel to gain read-only access to patient profiles.

e. The contractor shall provide to the Contracting Officer and the Lead Agent pharmacy report(s) as requested. The report(s) shall be submitted in the format as mutually agreed upon between the contractor, the Lead Agent, the Contracting Officer's Representative (COR) / Alternate Contracting Officer's Representative (ACOR), and the Contracting Officer, within 10 calendar days following receipt of the request.

B. Benefits

1. Labeled Indications. Drugs may be cost-shared when:

a. The drug is approved for marketing by the U.S. Food and Drug Administration

b. The drug is prescribed by a TRICARE authorized provider for its labeled indication

c. The drug is furnished by a TRICARE provider in accordance with all applicable state laws and licensing requirements

2. Off-label use. Drugs may be cost-shared for off-label uses when the managed care support contractor has determined that reliable evidence demonstrates such usage is safe and effective. As presented in order of relative weight in 32 CFR 199.2, reliable evidence means:

a. Well controlled studies of clinical meaningful endpoints, published in refereed medical literature

b. Published formal technology assessments

c. Published reports of national professional medical associations

d. Published national medical policy organizations.

e. Published reports of national expert opinion organizations

3. Drugs grandfathered by the Federal Food, Drug and Cosmetic Act of 1938 may be cost-shared as if FDA approved.

4. Insulin and related supplies may be cost-shared for diabetic patients, regardless of whether or not a prescription is required under state law.

5. Orphan Drugs. Drugs with FDA "orphan drug" designation and marketing approval may be cost-shared when used in the treatment of a rare disease or condition.

TRICARE defines a rare disease or condition as one which affects fewer than 1 in 200,000 Americans.

6. Vitamins may be cost-shared only when used as a specific treatment of a medical condition.

II. EXCLUSIONS

A. Drugs prescribed or furnished by a member of the patient's immediate family.

B. Drugs, including compounded preparations, that are available over the counter.

C. Group C Designation. Investigational drugs with FDA "Group C" designation have reproducible efficacy in one or more specific tumor types. Such a drug has altered or is likely to alter the pattern of treatment of the disease and can be safely administered by properly trained physicians without specialized supportive care facilities. TRICARE may not cost-share use of Group C designated drugs because authorization for Group C distribution for a specific indication is not equivalent to formal FDA approval for that indication. Medical care related to the use of Group C designated drugs may be cost-shared only when the care would have been provided in the absence of the use of the Group C designated drug.

D. Orphan drugs without marketing approval, but which are made available on a compassionate use basis, may not be cost-shared.

E. Treatment Investigational New Drugs (IND). Under the FDA treatment IND (investigational new drug) regulations enacted in 1987, drugs that are in controlled clinical trials can be provided outside those trials to treat patients with serious or immediately life-threatening diseases for which no comparable or satisfactory alternate therapy exists. TRICARE may not cost-share treatment INDs because they have not received FDA marketing approval. Medical care related to the use of treatment INDs may be cost-shared only when the care would have been provided in the absence of the use of the treatment IND.

III. EFFECTIVE DATE

A. Labeled uses: the date of FDA approval for the specific indication.

B. Off-labeled uses: the date that reliable evidence establishes the safety and efficacy of the drug for that specific use.

C. Orphan drugs: the date of FDA marketing approval.

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